

Translation

PATENT COOPERATION TREATY

PCT/JP2003/012345



PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference NUB-03-PCT	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/JP2003/012345	International filing date (<i>day/month/year</i>) 26 September 2003 (26.09.2003)	Priority date (<i>day/month/year</i>) 27 September 2002 (27.09.2002)
International Patent Classification (IPC) or national classification and IPC A61C 11/00, 19/04		
Applicant NIHON UNIVERSITY		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of <u>7</u> sheets, including this cover sheet. <input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT). These annexes consist of a total of <u>21</u> sheets.
3. This report contains indications relating to the following items: I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input checked="" type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input checked="" type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input type="checkbox"/> Certain observations on the international application

Date of submission of the demand 26 September 2003 (26.09.2003)	Date of completion of this report 19 May 2004 (19.05.2004)
Name and mailing address of the IPEA/JP Facsimile No.	Authorized officer Telephone No.

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I. Basis of the report

1. With regard to the elements of the international application:*

- ☐ the international application as originally filed
- ☒ the description:
pages 1-3,16-43, as originally filed
pages _____, filed with the demand
pages 4-15, filed with the letter of 23 February 2004 (23.02.2004)
- ☒ the claims:
pages 2-5,7,9-14,16,18,24-29,32-37, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages 1,6,8,15,17,19,22,23,30,31,38,40, filed with the letter of 23 February 2004 (23.02.2004)
- ☒ the drawings:
pages 1-45, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☐ the sequence listing part of the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☒ the claims, Nos. 20,21,39,41,42
- ☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

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III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 17, 18

because:

☐ the said international application, or the said claims Nos. _____
relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 17, 18

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

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IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

- ☐ restricted the claims.
- ☒ paid additional fees.
- ☐ paid additional fees under protest.
- ☐ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

- ☐ complied with.
- ☒ not complied with for the following reasons:

The common "special technical feature" of the inventions of claims 1-14, 19, and 22-37 is "the external outlines of both the head of the prosthetic joint and the cavity of the prosthetic joint have the same shape as the outlines of the head of the temporomandibular joint and the cavity of the temporomandibular joint of the person from whom the impression was taken when preparing the mold of the upper teeth" and "the head of the prosthetic joint and the cavity of the prosthetic joint are constructed by a three-dimensional model formed by an imaging device."

The common "special technical feature" of the inventions of claims 15, 16, and 40 is "the face bow main body is made of an X-ray permeable material and it also provides a marking member consisting of an X-ray non-permeable material opposed in a left-right direction to the center or vicinity thereof of the temporomandibular joint of the patient at a position anterior to the ear rods and a support member that supports each leg member of the marking member."

The "special technical feature" of the invention of claim 38 is "providing a database that contains ideal-model data of the head of the temporomandibular joint and providing a data correcting means that corrects the three-dimensional image data of the temporomandibular joint member specified by data imaged by a CT device such that the outline of the temporomandibular joint specified by the data imaged by the CT device becomes a filled-in such that it approaches the ideal model when a comparison is performed between the exterior outline of the heads of the temporomandibular joint from among the temporomandibular joint members specified by the data imaged by the CT device and the corresponding ideal model in the database, and it is judged that the heads of the joint have more than a specified amount of wear."

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- ☐ all parts.
- ☒ the parts relating to claims Nos. 1-16, 19, 22-38, 40

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-16, 19, 22-38, 40	YES
	Claims		NO
Inventive step (IS)	Claims	4, 5, 15, 16, 24, 25, 31-38, 40	YES
	Claims	1-3, 6-14, 19, 22, 23, 26-30	NO
Industrial applicability (IA)	Claims	1-16, 19, 22-38, 40	YES
	Claims		NO

2. Citations and explanations

Document 1: JP 6-90967 A (Ormco Corp.) April 5, 1994
Document 2: JP 48-10869 B1 (Yasunari Hobosu) April 7, 1973
Document 3: JP 41-16679 B1 (Kenneth H. Swanson) September 21, 1966
Document 4: JP 11-249548 A (Masayuki Koizumi) September 17, 1999
Document 5: JP 41-7034 B1 (Charles Edward Stewart) April 19, 1966
Document 6: WO 00/59401 A1 (Lorenzo Battistutta) October 12, 2000
Document 7: JP 9-220237 A (Shiyuukai Foundation) August 26, 1997
Document 8: JP 2002-264222 A (Minolta, Ltd.) September 18, 2002

Based on the descriptions in documents 1-3 cited in the international search report, the inventions of claims 1-3 and 6-13 lack an inventive step.

Documents 1-3 describe an occludator with variable shapes for the head of the joint and the cavity of the joint.

More specifically, based on the description on page 7, left column, lines 15 to 24 of document 1, this examination finds that it is suggested that the shapes of the head of the temporomandibular joint and the cavity of the temporomandibular joint approach the shapes of the temporomandibular joint of the patient.

In addition, this examination finds that the means of fixation such as described in claims 6-9 are conventional means of fixation, and their use in the inventions of documents 1-3 is obvious to persons skilled in the art.

Based on the descriptions in documents 1-3 and 5 cited in the international search report, the invention of claim 14 lacks an inventive step.

It is obvious to persons skilled in the art to combine the occludator described in documents 1-3 with the face bow that has ear rods described in document 5.

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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of Box III:

No international search report was prepared for the face bow that "provides a restricting mechanism that allows the left-right pair of leg members to slide only in the left-right direction" described in claims 17 and 18.

In addition, this examination finds no technical relationship that contains the same or corresponding "special technical features" between the invention of claim 17 and the inventions of claims 1-16, 19, 22-38, and 40.

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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of Box V:

Based on the descriptions in documents 1-4 and 7 cited in the international search report, the inventions of claims 19, 22, 23, and 26-30 lack an inventive step.

In the occludators described in documents 1-3, it is obvious to persons skilled in the art to apply the technology described in document 4 of forming a temporomandibular joint by optical prototyping and to apply the technology in document 7 of selecting an optimal model by comparing the three-dimensional data obtained from the CT scan with the data contained in the database and performing optical prototyping based on that model.

Moreover, this examination finds no constitutional difference as an "object" between a temporomandibular joint in which a dissociable shape is formed as one unit and then dissociated thereafter and a temporomandibular joint that is simply formed.

The mounting means as described in claims 4, 5, 24 and 25 is not described in any of the documents cited in the ISR; nor is this obvious to persons skilled in the art.

None of the documents cited in the international search report describes the face bow of claims 15, 16, 31-37 and 40 that has a marking member that is formed of a material that is impermeable to the X-rays used in an X-ray or CT apparatus, and this matter is not obvious to persons skilled in the art.

None of the documents cited in the international search report describes making a decision that a joint head is worn and forming the joint head by adding a correction to the outline shape of the joint head as described in claim 38, and this matter is not obvious to persons skilled in the art.